Brooklyn Law Review

Volume 73
Issue 3
SYMPOSIUM:
A Cross-Disciplinary Look At Scientific Truth:
What's The Law To Do?

Article 4

2008

Truth, Epidemiology, and General Causation

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INTRODUCTION

Does epidemiology, a basic science of disease causation, seek and find the truth? Certainly there are those who say it does: physicians,[1] epidemiologists,[2] even lawyers.[3] Many philosophers of science these days, on the other hand, are extremely skeptical of claims to scientific truth.[4] And were it not for some important practical matters facing epidemiologists in the courtroom and in other parts of our professional practice,

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I want to acknowledge the helpful comments of Dr. Michelle Althuis in the preparation of this paper.

[1] For a discussion of the role of epidemiology "in the search for clinical truth," see, e.g., Ann M. Kosloske, *Epidemiology as the Search for Truth*, 11 SEMINARS IN PEDIATRIC SURGERY 162, 162 (2002).

[2] As one epidemiologist stated in a discussion of post-viral fatigue syndrome:

> For many, [post-viral fatigue syndrome] represents a "rag bag" diagnosis into which unsolved diagnostic problems are discarded. Others are in no doubt that there is a discrete syndrome, probably with a specific causation. The real answer almost certainly lies somewhere in between, but the truth can only be established through epidemiological studies designed to answer key questions.

P.G. Wallace, *Epidemiology: A Critical Review*, 47 BRIT. MED. BULL. 942, 942 (1991).

[3] "Both law and science are truth-seeking endeavors. In at least one respect, lawyers and scientists are like Agent Mulder on the 'X-Files': we believe that the truth is out there and our goal is to find it." Arthur H. Bryant & Alexander Reinert, *Epidemiology in the Legal Arena and the Search for Truth*, 154 AM. J. EPIDEMIOLOGY (SUPP.) S27, S27 (2001).

[4] For example, Peter Lipton writes:

> The status of the truth hypothesis [according to which, science is generating increasingly accurate representations of a mind-independent and largely unobservable world], and so of realism, thus remains unsettled: it is neither undermined by the pessimistic induction nor confirmed by the miracle argument. Nor do I know of any other arguments that even come close to closing the question. This suggests that the rational attitude towards a scientific theory should never rise above the level of agnosticism.

Peter Lipton, *The Medawar Lecture 2004: The Truth About Science*, 360 PHIL. TRANSACTIONS ROYAL SOC'Y B 1259, 1268 (2005).

we could leave it at that; epidemiologists seek the truth but have no theoretical justification for saying they have found it. Seeking the truth and actually obtaining the truth, in other words, are different activities evaluated in very different ways. The problem with this perspective is that those who rely on claims about disease causation—the patients, the public at large, and the litigants—may prefer that the professionals who have promised to help them—the physicians and epidemiologists, for example—act with "truth" rather than a "search for truth" on their side. At stake for all these individuals are actions that can change lives in profound ways: therapeutic decisions, public health recommendations, and legal opinions.

One popular escape from this conundrum is for epidemiologists (and any others who both do the science and use it) to lay claim to something close to the truth rather than truth itself. When asked about whether they have actually obtained the truth, epidemiologists typically do a little back-pedaling and say that they are only more-or-less certain about what is true. They say that their claims about what causes diseases are only approximations to the truth. In doing so, they allow themselves the luxury of never actually dealing with the nature of truth as such. They need only assert that they are trying to reach the truth and believe that they are somewhere close to achieving it. But they never actually find the truth. In the end, they are only more or less certain about being more or less close to the truth.

This approach seems to have worked pretty well in the practice of medicine and public health where no one ever promised to provide the truth in the first place. Promises are made, but not about the truth. Epidemiologists, for example, promise to prevent disease. Physicians promise to treat disease. Neither profession, however, promises to provide the truth about the scientific theories that undergird their respective practices.[5] When pushed on this point, they will only

[5] The idea that promises are made to society by epidemiologists and physicians emerges from the discussion of the nature of these professions in contemporary society. As I have described:

> [M]odern professions are recognized by a common education, a common ethic, and professional standards. But at a deeper level, professions are characterized by whom they serve and what promise they make to assist those served. The original meaning of the word "profession" is to "declare publicly," thus, professional declare they have special knowledge, they can help, and they will do so in the interest of others. Examples include physicians, teachers, and ministers. In each case, the professional fulfills a

say that they seek the truth and that they are more or less certain that they are somewhere near it.

The practice of law is another matter altogether. In the courtroom, when epidemiologists (and physicians and many others) provide expert testimony on disease causation in toxic tort litigation, they swear to tell the truth, the whole truth, and nothing but the truth. What does it mean, then, for epidemiologists (and for jurisprudence) if they make such a promise but only seek some approximation to the truth—something more or less close to the truth—rather than actually ever finding it?

My purpose in this essay is to examine this issue in terms that will require a critical assessment of the nature of truth in epidemiology. Of particular interest here is the role of truth in solving the problem of disease causation, the central scientific problem of the profession and a key concern in toxic tort litigation. I will limit my remarks to general causation, leaving aside causation in individuals, that is, specific causation.[6]

In Part I, I briefly discuss "telling the truth" well beyond the need for honesty and prohibitions against falsification and fabrication in the practice of science but also in the business of expert testimony. Telling the "truth" about science is to tell what has been published in the scientific literature, no more and no less. This is the truth of studies and their results and the methods used to obtain those results. In Part II, I discuss the implications of "telling the whole truth." The whole truth, in this context, must include not only the so-called original published studies but also the commentaries on those studies. These typically appear as systematic reviews, editorials, and

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> promise inherent in the act of profession by making a claim and by following up on that claim by specific actions that identify that profession. Thus physicians claim to restore health through the central act of healing . . . . [and epidemiologists] claim to prevent disease.

Douglas L. Weed, *Science, Ethics Guidelines, and Advocacy in Epidemiology*, 4 ANNALS EPIDEMIOLOGY 166, 169-70 (1994) (endnote omitted). For a more comprehensive account of the role of the physician in modern society, see generally Edmund D. Pellegrino, *Toward a Reconstruction of Medical Morality: The Primacy of the Act of Profession and the Fact of Illness*, 4 J. MED. & PHIL. 32 (1979).

6 To consider the problem of general causation is to consider whether an agent (e.g., an exposure factor) is capable of causing disease, typically in a population. Michael D. Green et al., *Reference Guide on Epidemiology*, *in* FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 333, 392 (2d ed. 2000). Specific causation, on the other hand, involves considering whether exposure to an agent was responsible for a single individual's disease. *Id.* at 396.

other publications, including textbook chapters, where the studies' strengths and weaknesses are described and where evidence is summarized, synthesized, and interpreted, for the purpose of making claims about causation. It is increasingly accepted in the practice of epidemiology that a systematic narrative review of the evidence is the appropriate venue for assessing cause and for making claims about disease causation. In Part III, I explore the most controversial component of the honesty oath: telling "nothing but the truth." This will require a serious reconsideration of the nature of truth in epidemiologic science. I discuss the extent to which those components of the practice of epidemiology that transcend its written historical record can be considered true: the aims and values of its practitioners, their modes of reasoning, the theories and philosophies used to help solve the problem of general causation, as well as the causal claims themselves, whether published or not. Of particular importance is the fact that expert testimony goes beyond that which has been published. It can only be true in the same sense that published studies and published causal assessments are true if the expert applies the same methods and rigor to his testimony as that which is required for results and causal claims to appear and to be accepted in the peer-reviewed literature.

I. THE TRUTH

At first glance, no single concept seems better suited for what a scientist believes is her ultimate aim than the truth. The search for truth in science is legendary.[7] It is a search for the really real, a search to separate fact from fantasy. The

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[7] Philip Kitcher writes about science and its search for truth as a point of view so popular and important that he dubs it "Legend." PHILIP KITCHER, THE ADVANCEMENT OF SCIENCE: SCIENCE WITHOUT LEGEND, OBJECTIVITY WITHOUT ILLUSIONS 3 (1993). He notes that there have been

> differences among the versions of Legend. Some thought in ambitious terms: ultimately science aims at discovering the truth, the whole truth, and nothing but the truth about the world. Others preferred to be more modest, viewing science as directed at discovering truth about those aspects of nature that impinge most directly upon us, those that we can observe (and, perhaps, hope to control). On either construal, discovery of truth was valued both for its own sake and for the power that discovery would confer upon us.

Id.

search for truth is an independent and objective assessment of what is "out there" in the world in which we live.[8]

Or so we have been told, over and over, by those who have trained us. I realize now, however, some thirty years after the last lecture in graduate school, that no one ever explained to me during my scientific training what exactly this thing called the "truth" is. Indeed, no one has ever held something up in front of me, much less an entire audience at an international congress of epidemiology, and declared: *This* is the truth! *We have found it!* To put it more bleakly, no one has ever even proclaimed: *This* is the truth that we seek!

Nevertheless, scientists seem to deeply appreciate their special relationship to the truth. When they proclaim that they are in pursuit of the truth, they do not think that truth is a temporary stamp of approval or, at worst, merely a compliment that can be revoked.[9] No. The truth that science seeks—when we hear that it has gone hunting—is a permanent special something, something to believe in and something to put our faith in. Small wonder there are those who align science with religion, as both seem to be in search of something that passes beyond understanding, yet still explains who we are, why we are here, how we live, why we get sick, and how we die.[10]

Perhaps it would help matters here to offer a definition of truth. The influential philosopher of science, Karl Popper, never a friend of definitions,[11] nevertheless accepted what he

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8 The scientist's favorite philosopher, Karl Popper, created three worlds: "the physical world 'world 1', the world of our conscious experiences 'world 2', and the world of the logical contents of books, libraries, computer memories, and suchlike 'world 3'." KARL R. POPPER, OBJECTIVE KNOWLEDGE: AN EVOLUTIONARY APPROACH 74 (1972). The world "out there" is world 1, the physical world.

9 Richard Rorty, the somewhat radical neo-pragmatist, has expressed the view that the term "true" is merely a compliment or commendation for one's point of view. He writes, "The pragmatist . . . . feels free to use the term 'true' as a general term of commendation in the same way as his realist opponent does—and in particular to use it to commend his own view." 1 RICHARD RORTY, OBJECTIVITY, RELATIVISM, AND TRUTH: PHILOSOPHICAL PAPERS 23 (1991).

10 Rorty opines, for example, that we live in a secular world in which the scientist has replaced the priest. "The scientist is now seen as the person who keeps humanity in touch with something beyond itself." *Id.* at 35.

11 Karl Popper writes:

> One should never get involved in verbal questions or questions of meaning, and never get interested in words. If challenged by the question of whether a word one uses really means this or perhaps that, then one should say, "I don't know and I am not interested in meanings; and if you wish, I will gladly accept *your* terminology." This never does any harm. One should never quarrel about words and never get involved in questions of terminology.

POPPER, *supra* note 8, at 309-10.

called a common sense definition of truth: that which corresponds with the facts.[12] With this definition, we can proceed as long as we have facts. For example, with this definition in hand, how can we not accept the truth of some well-accepted claims: the existence—the fact—of cancer, the existence—the fact—of viruses, and the claim (also a fact?) that a virus can cause cancer? To be specific, do we not accept as true that the human papillomavirus establishes itself in the deep recesses of the cells lining the cervix and then transforms some unlucky cell into something uncontrollable, malignant, and deadly? Do we not accept as fact and so true that the human papillomavirus causes cervical cancer?[13]

This final question is a tough one to answer truthfully. For we have seen the cancer and the virus with our own eyes in photos of malignant cells from pathologists' slides and electron microscopic images of the virus. These we take to be true. And we might also accept as true the explanation that this cancer is caused by this virus, if it were not for the fact that we have not seen causation. Nowhere in the peer-reviewed literature, in the tables, nor in the graphs and figures displayed in all the studies that have been published, can we find this thing called "causation." Not one of these shows us that, in fact, human papillomavirus causes cervical cancer. Not one. To tell you the truth, we have seen causation only in words.

There are many examples of this phenomenon. There are many such causal claims, many more now than there were a few decades ago, that can be found in this same peer-reviewed literature, alongside the photos of the viruses and the mutated genes—the exposures—and the cancers and other diseases—the outcomes—and I believe these to be statements that those who wrote, reviewed, edited, and published them believe are true, these statements that some exposure caused some outcome. But this is a different sort of truth, is it not, than the truth we assign to the photos and the tables, the graphs, the figures, and the numbers themselves, and to the

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[12] "[W]e can define, purely verbally, yet in keeping with common sense: *A statement is true if and only if it corresponds to the facts.*" *Id.* at 46 (footnote omitted).

[13] It is generally believed that human papillomavirus infection causes most cervical cancer. *See* Eduardo L. Franco, Editorial, *Cancer Causes Revisited: Human Papillomavirus and Cervical Neoplasia*, 87 J. NAT'L CANCER INST. 779, 779-80 (1995); Mark H. Schiffman et al., *Epidemiologic Evidence Showing That Human Papillomavirus Infection Causes Most Cervical Intraepithelial Neoplasia*, 85 J. NAT'L CANCER INST. 958, 958-64 (1993); *see also* Robert C. Millikan, Correspondence, 86 J. NAT'L CANCER INST. 392, 392-93 (1994) (letter regarding Schiffman et al., *supra*).

existence—the fact—of the causal claims themselves that sit there to be read in the peer-reviewed literature?

The photos and all the rest, including the causal claim, are true in the sense that they were recorded at a certain point and place in time and will remain there for perpetuity, barring some unnatural calamity along the lines of the great fire at the Alexandria library. Anyone can see them. There is also a clear trail for each back to its origin. The photo of the virus came from a laboratory where a researcher turned on an electron microscope to take a snapshot of the parasite in all its symmetrical and deadly beauty. Likewise, a pathologist photographed the cells of a tumor that a surgeon carefully cut from the cervix of a woman who had the bad luck to be so afflicted. Finally, there is the author of the claim itself—that this virus causes that cancer—perhaps the same surgeon who also trained in epidemiology (a rare individual). Each of these individuals has a name—the laboratory researcher, the pathologist, the surgeon, and the patient herself—and their contributions to the existence of the photos and the sentence (all of which could have appeared in the same review article about human papillomavirus and cervical cancer) can be documented, verified, observed directly, and accepted without any uncertainty at all. These really are truths, plain and not so simple.

But the causal claim itself—that this type of virus caused that sort of cancer—does not have this same sort of connection back to some unique event that can be documented, verified, and directly observed. The causal claim is a scientific hypothesis and we cannot ever know if it is true in the same sense as the existence of the virus, the cancer, and its author. The hypothesis can be well supported or not by the available evidence. It can be more or less certain, more or less proven, but it cannot ever be true. The reason is remarkably straightforward. Causation cannot be seen. Causation cannot be proven. And the evidence for causation always underdetermines our capacity to choose between the causal hypothesis of interest and its various alternatives.[14] Nor can

[14] Causal hypotheses, however much we believe in them and regardless of how much scientific evidence supports them, can never be true. This remarkable claim can best be understood by explaining how the scientific practice of making claims about disease causation is affected by three fundamental (causal) problems. These problems, which can also be considered constraints on scientific practice, affect anyone who examines scientific evidence for the purpose of making causal claims. Like a plague, these constraints are not negotiable. They involve, but are not limited to, the extent to

which we can see (observe) the thing we call "causation" and the extent to which we can prove any causal hypothesis. In the end, these constraints prohibit us from claiming that scientific hypotheses about disease causation are true. For the purposes here, I refer to these three problems (or constraints) as (1) the fundamental problem of causal inference, (2) the fundamental problem of causal logic, and (3) the fundamental problem of causation.

First, the fundamental problem of causal inference is that we cannot observe on the same individual both the effect of a cause (e.g., a disease outcome) and what would have occurred had the cause not acted to produce its effect. *See generally* Paul W. Holland, *Statistics and Causal Inference*, 81 J. AM. STAT. ASS'N 945 (1986). This constraint is sometimes called the "counterfactual" condition. If, for example, an individual begins taking a new medication and is later diagnosed with an illness or condition, we cannot know if that person would have contracted that illness or condition without taking the medication. This fundamental problem of causal inference is the primary reason why randomized clinical trials are considered the gold standard of scientific research in therapeutic and preventive clinical research; randomized trials provide the best approximation to solving this problem by assuming that the individuals who do not receive the medication or other intervention (e.g., the placebo controls) are as similar as possible to the individuals who do receive the intervention. Certainly, the control group is not exactly the same as the treated group, but randomization assures that the differences between the two groups are distributed evenly between them.

This fundamental problem of causal inference also explains why control groups in any study of human health effects are so important. Epidemiological studies do not randomly identify controls, but controls are carefully selected, nevertheless, for precisely the same reason they are used in randomized trials: to provide an approximate solution to this fundamental problem. Claims about disease causation from studies that lack control groups are of questionable validity and reliability.

The second constraint, the fundamental problem of causal logic, is also known as the problem of "underdetermination." Underdetermination means that the available scientific evidence cannot once-and-for-all determine which hypothesis is the true hypothesis among all those involved in a particular situation, such as the main causal hypothesis, alternative causes, and chance. It is a straightforward if frustrating fact that scientific tests of causal hypotheses cannot provide proof or disproof. By "proof" I mean the sort of absolute proof found in mathematics and symbolic logic, the kind of proof that cannot be questioned. *See generally* Ernan McMullin, *Underdetermination*, 20 J. MED. & PHIL. 233 (1995); Douglas L. Weed, *Underdetermination and Incommensurability in Contemporary Epidemiology*. 7 KENNEDY INST. ETHICS J. 107 (1997), *available at* http://muse.jhu.edu/journals/kennedy_institute_of_ethics_journal/v007/7.2weed.html. The available scientific evidence always underdetermines the choice of the best hypothesis that explains that evidence.

Underdetermination implies that there is always room for questioning the validity and reliability of any scientific test of any scientific hypothesis. Causal hypotheses in medicine—such as the hypothesis that a medication (such as pramipexole) causes a condition (such as pathological gambling)—are never proven nor disproven in a scientific sense. Put another way, the available scientific evidence underdetermines the choice between the various alternative hypotheses that can explain that evidence. A randomized controlled clinical trial, for example, is a very strong test of a causal hypothesis, but it does not prove—once and for all—that a factor (e.g., a treatment) causes an outcome (e.g., a cure). That does not mean, of course, that we do not use a medication once a randomized trial has shown it to be effective; acting on the basis of the results of a trial and using the results of a trial as proof of a scientific hypothesis are two very different phenomena, an important point to which I will return. Case series, on the other hand, are extraordinarily weak—essentially irrelevant and highly unreliable—tests of causal hypotheses; they cannot help us to choose between the alternative hypotheses. A "case series" is a report of a collection (or group) of individual patients who have experienced a disease or other adverse event and were also exposed to some purported causal exposure (e.g., a medication or a causation be made certain. It is, at best, an expert's judgment, at worst, an expert's guess.[15]

This is what I take to be the true that I, as an epidemiologist appearing in court to provide expert testimony, can swear to: that exposures exist, that outcomes exist, and that causal claims exist. One can also swear that there is evidence—scientific studies—linking the exposures to the outcomes (or not). And there are methods used in the design, analysis, and interpretation of those studies—methods both quantitative and qualitative, methods analytical and synthetic, methods of science, of epidemiology, of statistics, and of philosophy itself. That is the truth and nearly the whole truth.

II. THE WHOLE TRUTH

Telling the truth is telling that which corresponds with the facts. This telling of scientific facts is so straightforward and clear that it is unquestionable at best and, perhaps for some, unremarkable at worst. The facts of any case of disease causation include the published reports of studies designed to

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chemical). A case series has no controls, that is, no comparison group. It is impossible to use a case study or a case series to distinguish between one cause and another explanation for the same outcome, as was explained in my description of the fundamental problem of causal inference.

The final constraint, the fundamental problem of causation, is the most important of all and is the most basic. Simply put, causation cannot be seen. Causation itself is not observable. Steven N. Goodman & Jonathan M. Samet, *Cause and Cancer Epidemiology*, *in* CANCER EPIDEMIOLOGY AND PREVENTION 3, 3-9 (David Schottenfeld & Joseph F. Fraumeni eds., 3d ed. 2006). We do not—cannot—see a chemical cause cancer, nor do we see a virus cause pneumonia. We cannot see a medication cause an adverse event. We can certainly measure the exposure to the medication, and we can certainly measure the adverse event, the outcome, but we cannot see causation. Critics may quickly point out what they believe to be a strong counterargument: do we not see that a rock thrown through a window causes the window to shatter? The great British philosopher David Hume pointed out that even in this situation, we still do not actually see the thing we call "causation." We see the rock. We see it fly through the air. We hear the rock strike the window. We see the window shatter. But we do not actually see causation. *See* Joseph Agassi, *Causality and Medicine*, 1 J. MED. & PHIL. 301 (1976). If we cannot see causation in these everyday circumstances, then it is even more obvious that causation cannot be seen when a medication appears to cause an adverse event. We can certainly see the medication being taken. We can (often much later) see that an adverse event has occurred. But nowhere along that continuum do we actually see causation. It is the evidence—our scientific observations—that we "see," not causation.

15 "[Judgment] is regularly invoked when scientific evidence is used to make a claim about disease causation in the courts or in regulatory risk assessment." Douglas L. Weed, *The Nature and Necessity of Scientific Judgment*, 15 J.L. & POL'Y 135, 135 (2007). Indeed, judgment is probably always used in any such assessment. "[S]cientific judgment is not easy to define, although we are fairly clear about the kind of judgment we prefer: good, sound, and unbiased." *Id.* at 140. It is reasonable to assume that some scientists' judgments are better than others.

describe the exposure and the disease in question as well as those studies designed to test the hypothesis that the exposure caused the disease. In order to approach the "whole truth," however, to these studies we must add the reviews—ideally, systematic narrative reviews—of those studies where searching, selection, summarization, and interpretation in causal terms occur. Reviews are critically important publications. Within these reviews (and commentaries, editorials, textbook chapters, and even letters to the editor), experts discuss their positions on issues including internal and external validity, methodological concerns (both quantitative and qualitative), as well as sources of funding, ethics, and practical implications of the research findings under review. These all count as facts, in a very broad sense, scientifically.

Curiously enough, both science and the law share this feature; careful records of events are kept in both: studies, reviews, and commentaries in science, and cases, opinions, and commentaries in the law. On the science side, we could also add the textbooks, popular (media) commentary, and last, but certainly not least, what philosophers of science think about the whole complex and lengthy business just described. If by "facts" we mean that which has been published, then there is only one (major) problem for the expert who raises his hand and swears to tell the truth and nothing but the truth: just how much of this written record really matters?

It is no secret that, in practice, science sees this issue—what evidence really matters in assessing causation—differently than does the law. The rules for selecting the truth (as historical record) differ in these two practices. Scientific assessments tend to be much more inclusive than those in some courts, where judges have the power to accept and reject (as inadmissible) every potential "fact" that the parties bring to their attention, subject to the laws of evidence. There are many examples of courts selectively rejecting as inadmissible scientific evidence that would typically be included in a systematic review in the practice of epidemiology.[16]

While the admissibility of facts is governed by the rules of evidence in the law, science too has rules regarding the

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[16] For two different accounts of the admissibility issues post-*Daubert* in the context of general causation in matters relating to health, see Joe S. Cecil, *Ten Years of Judicial Gatekeeping Under* Daubert, 95 AM. J. PUB. HEALTH (SUPP. 1) S74 (2005); Ronald L. Melnick, *A* Daubert *Motion: A Legal Strategy to Exclude Essential Scientific Evidence in Toxic Tort Litigation*, 95 AM. J. PUB. HEALTH (SUPP. 1) S30 (2005).

inclusion and exclusion of facts for consideration in an assessment of disease causation, as well as rules covering which studies to include in a systematic narrative review, a process that has been evolving from around the mid-1980s to the present.[17] Today, a systematic narrative review is a careful and transparent process involving the use of search terms and databases, and inclusion and exclusion criteria. The process includes searching (in some instances) for not-yet-published studies and studies required by regulatory agencies but never published, and lengthy discussions about the quality and validity of these same studies, published or not, but worthy of publication nevertheless.[18] This process of systematically reviewing all (or nearly all) the evidence has become standard accepted practice in epidemiology and medicine, indeed, in all the biomedical sciences save perhaps for the so-called basic (laboratory) sciences—molecular biology, toxicology, etc.—which tend to produce interesting and important but not-so-systematic reviews of disease mechanisms.

A central purpose of a systematic review is to determine if the available evidence sufficiently supports and/or warrants a claim of causation. Causal claims, in theory, could be—have been—made based on the results of single studies and, indeed, based on reports of adverse events in single individuals, but these are rare and unusual circumstances and, to put it bluntly, more likely decisions about what needs to be done (to protect the public's health) than well-tested claims about causation.[19] Causal claims typically require a body of evidence comprised of many studies from different disciplines along with

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[17] For an example of methodological guidelines for systematic reviews, see Douglas L. Weed, *Methodologic Guidelines for Review Papers*, 89 J. NAT'L CANCER INST. 6 (1997).

[18] A systematic review of the evidence is one of several "weight of evidence" methods. *See* Douglas L. Weed, *Weight of Evidence: A Review of Concept and Methods*, 25 RISK ANALYSIS 1545 (2005).

[19] The use of case reports—that is, reports of an adverse event in a single individual or a series of individuals (also known as a case series)—as scientific evidence to withdraw a medication from the market is discussed and debated in the area of pharmacovigilance. *See* J.A. Arnaiz et al., *The Use of Evidence in Pharmacovigilance: Case Reports as the Reference Source for Drug Withdrawals*, 57 EUR. J. CLINICAL PHARMACOLOGY 88, 88-91 (2001); Bruno H.Ch. Stricker & Bruce M. Psaty, *Detection, Verification, and Quantification of Adverse Drug Reactions*, 329 BRIT. MED. J. 44, 44-47 (2004); Jan P. Vandenbroucke, *Case Reports in an Evidence-Based World*, 92 J. ROYAL SOC'Y MED. 159, 159-63 (1999); Geoffrey R. Venning, *Identification of Adverse Reactions to New Drugs III: Alerting Processes and Early Warning Systems*, 286 BRIT. MED. J. 458, 458-60 (1983).

the methods of causal inference used to summarize and interpret that evidence.

Given the thoroughness of systematic reviews and their centrality in the fields of epidemiology and medicine, it follows that they are not only important facts to be considered in an expert's testimony, but the single most important facts, the single most important truths, to be recounted, examined, and critiqued. And that brings us to the final component of the honesty oath: "nothing but the truth." For if the "truth" is that which has already appeared in print, what is left for the expert if he has already told that truth, indeed the whole truth with the studies and the reviews and commentary and all the rest? What remains if that expert has promised to tell "nothing but the truth?"

III. NOTHING BUT THE TRUTH

As long as we maintain the premise that the truth of science is that which has been published—as carefully recorded historical events—then the expert who promises to tell nothing but the truth has apparently no greater role in the proceedings than any other reporter of events. In this situation, the scientific expert provides an account of the studies that have measured exposures and diseases and have combined that information in such a way that the causal hypotheses of interest were more-or-less tested. He also provides an account of the commentary on those studies, and, most importantly, he provides an account of the systematic reviews of those same studies, with their causal claims, recommendations for actions, and/or recommendations for more research.[20]

The only way the expert's opinions on these matters—his own assessment of the relevance, reliability, and validity of the evidence, the commentaries, and especially the systematic reviews and their claims—can be considered "true enough" is if

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[20] As I have written elsewhere,

> [Systematic] literature reviews . . . are a longstanding form of synthetic method and are ubiquitous in science, appearing in peer-reviewed journals, in textbook chapters, and in background material for research funding applications. The purposes of systematic reviews can include: claims regarding general causation, efficacy of therapeutic or preventive interventions, recommendations for such interventions, and recommendations for future research.

Douglas L. Weed, *Evidence Synthesis and General Causation: Key Methods and an Assessment of Reliability*, 54 DRAKE L. REV. 639, 646 (2006).

he presents them in a manner that would be acceptable in the practice of science, using the same methods of assessment, the same systematic search procedures, and the same criteria (or guidelines) for making causal claims. To be compatible with the promise to tell nothing but the truth, an expert's report for the court must be as well-prepared and carefully documented as a highly-regarded systematic review from any of the several institutions which regularly produce such reports: the Institute of Medicine ("IOM") in the United States, the Cochrane Collaboration in the United Kingdom, and the International Agency for Research on Cancer ("IARC") in France, to name only three.[21] The expert, in short, must opine as if he intends to submit his views for peer-reviewed publication, following reasonably well-established guidelines for transparent systematic reviews. Only then will his opinion on causation be true enough to be consistent with the promise he made to the court.

By no means am I suggesting that the current methods for making causal claims from scientific evidence (and I include here all types of relevant evidence, from human epidemiologic studies to lab-based toxicological studies) are without errors and thus free from the need for serious improvements.[22] Nor am I suggesting that the process of peer review in scientific publishing eradicates all errors—intentional, accidental, or fundamental. Far from it. Both processes can be (must be)

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[21] The Institute of Medicine, the Cochrane Collaboration, and the IARC regularly produce highly regarded systematic reviews of causation issues. For representative examples, see COMMITTEE ON ASBESTOS, INST. OF MEDICINE, ASBESTOS: SELECTED CANCERS (2006); Jimmy Volmink et al., *Research Synthesis and Dissemination as a Bridge to Knowledge Management: The Cochrane Collaboration*, 82 BULL. WORLD HEALTH ORG. 778 (2004); INT'L AGENCY FOR RESEARCH ON CANCER, WORLD HEALTH ORG., IARC SCIENTIFIC PUBL'N NO. 100, CANCER: CAUSES, OCCURRENCE AND CONTROL (L. Tomatis ed., 1990).

[22] As I have written elsewhere:

> It is no exaggeration to say that any epidemiologist who claims he is an expert—that he can reliably make claims about causation—is either hopelessly naïve or a flagrant prevaricator. As noted earlier, I do not mean to suggest that prior claims about what factors or exposures cause illnesses are incorrect.

Douglas L. Weed, *Causation: An Epidemiologic Perspective (In Five Parts)*, 43 J.L. & POL'Y 52, 43-53 (2003). My primary concern here is that a careful description of the methods of causal inference used in practice is an absolute necessity. It is also the case that these methods are in need of improvement. That does not mean that an individual epidemiologist cannot be an expert in the methodology of causation. My main message here is that the methods of causal inference need to be improved, and thus the user must recognize their limitations. Nevertheless, the best situation in practice is to comprehensively describe and systematically reference these methods when they are used. When no method is described, any causal claim is suspect.

improved. Both have a long way to go. The methods of causal inference, for example, which we use to synthesize and summarize the available scientific studies and which incorporate criteria (or guidelines) for interpreting the summarized evidence, are chock full of values—both scientific and extrascientific—of the practitioners who invented and use them.[23]

To be specific, consider the list of causal criteria (sometimes called considerations, aspects, or guidelines) used by epidemiologists, physicians, federal regulatory agencies, and just about everyone else (including toxicologists) who examines scientific evidence for the purpose of making causal claims. There are nine such criteria in traditional accounts. Hill's criteria, for example, were described by the medical statistician, Sir Austin Bradford Hill in 1965; they include strength, consistency, dose-response, biological plausibility, temporality, specificity, coherence, experimentation, and analogy.[24] Fundamentally, these are qualitative values with links (in some but not all instances) to quantitative results. They are values because we believe them to be that which matters when assessing the scientific evidence for causation. Other important scientific values are the concepts of relevance, reliability, validity, and statistical significance. Interestingly, Hill's criteria do not include any of the aforementioned concepts, nor do they include predictability or testability. That simple fact points out the complexity of the process. All these concepts/criteria/guidelines/values (or whatever else you want to call them) are important when making causal claims: relevance, reliability, validity, statistical significance, predictability, testability, consistency, strength, dose-response, plausibility,

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[23] As I have previously commented,

> [I]n the practice of causal inference . . . reviewers of scientific evidence come to opposite conclusions using methods that are quite similar on the surface, but quite different at deeper levels, where numerous choices are available regarding criteria, rules of inference, and other components of the methodology. Differing conclusions emerge because reviewers hold dear different scientific and extrascientific values that affect these choices.

Weed, *supra* note 14, at 122-23.

[24] Hill's criteria (or considerations) are one component of a general method of causal inference. For an account of Hill's criteria in the practice of causal inference in epidemiology, see Sir Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 PROC. ROYAL SOC'Y MED. 295, 295-305 (1965); Weed, *supra* note 22, at 43-53.

temporality, experimentation, specificity, coherence, and finally the lowly and much-maligned concept of analogy.[25]

It is beyond the scope of this paper to sort out the relationships among these various values, including how best to prioritize them, their definitions, and rules of inference. One point to be made here is that all have been used—explicitly and, more likely, implicitly—in the practice of causal inference over the past fifty years. They are important components of an overarching method of causal inference. To these facts I will swear. That is the truth, a part of the whole truth, and nothing but the truth.

SUMMARY

Perhaps it is obvious by now that I do not see the "truth" as the aim of epidemiology if by "truth" we mean some final, absolute, and uncriticizable set of certain statements about the causes of diseases. The truth of my science is that which has been recorded in its literature. I can relate to that truth as the whole truth, if I give special attention to the systematic reviews that provide an overall assessment of general causation. In turn, I can provide my own assessment of general causation in terms of the methods used to make such inferences, applied to the available evidence, including prior reviews. In doing so, I provide nothing but the truth.

The scientific aim of epidemiology is explanation rather than truth. These explanations arise from and are tested in the use of our analytical and interpretative methods as well as judgment. They are the best explanations we have today. We may choose to act upon them, or not.

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[25] It is an unfortunate fact that the authors of one of the most influential intermediary textbooks of epidemiology believe that analogy is at best an exercise in creative thinking. They suggest that if you cannot find an analogy between one potential causal association and another, you simply lack imagination. KENNETH J. ROTHMAN & SANDER GREENLAND, MODERN EPIDEMIOLOGY 24-27 (1998).